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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,317	08/20/2004	Tina Rademacher	RO0861US(#90568)	5171

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,317	RADEMACHER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 27-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 27-42* is/are rejected.

7)☒ Claim(s) *43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/09/08 has been entered.

Claim Rejections - 35 USC § 102

Claims 1, 2, 5-12, 15-18, 20, 21, 29-31 and 33-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732).

Falkenhausen teaches a rapidly disintegrating sheet or wafer dosage form having thickness of between 0.1-5 mm, the dosage form comprising matrix-forming polymers, active ingredients, and a carbon dioxide gas forming agent (paragraphs 0006, 0036 and claim 11). Polymers include cellulosic polymers, and water-soluble polysaccharide (abstract; paragraphs 0017-0020). The dosage form further comprises eucalyptus oil, peppermint oil, flavor, sweetener, other additives, and foams such as propylene glycol (paragraphs 0023-0030). The dosage form disintegrates in the oral cavity in the range from 10-30 second (paragraph 0009).

It is noted that Falkenhausen is silent with respect to the density of the dosage form. However, the burden is shifted to applicant to show that the dosage form of Falkenhausen does not exhibit the claimed properties, because Falkenhausen teaches the same dosage form using the same dosage structures. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

Claims 1-12, 15-21, 27-31 and 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732), in view of Pather et al. US 2003/0091629.

Falkenhausen is relied upon for the reason disclosed in the 102(a) rejection. Falkenhausen does not explicitly teach the claimed carbon dioxide forming substance.

Pather teaches an effervescing sublingual buccal dosage form comprising a drug, an additive, and an effervescent in an amount of about 5% to about 95% (abstract; and paragraph 0014). Pather further teaches effervescent includes sodium carbonate, and potassium carbonate (paragraph 0015).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Falkenhausen to include the carbon dioxide forming

substance such as sodium carbonate in an amount in view of the teaching of Pather to obtain the claimed invention. This is because Pather teaches the use of effervescent in such an amount to influence the permeability of the medicament across the buccal, sublingual, and gingival mucosa (paragraphs 0008 and 0009), because Pather teaches the use of sodium carbonate to evolve gas such as carbon dioxide gas (paragraphs 0015-0016), and because Falkenhausen teaches the desirability of using carbon dioxide gas forming substance.

Falkenhausen further does not teach the amount of water-soluble polymer. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The examiner is unable to determine any unexpected result over the claimed amount of polymer because Falkenhausen teaches the use of the same matrix-forming polymer to obtain a rapidly disintegrating film that has the same disintegration time, *i.e.*, 10-30 second (ID). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select an amount of matrix-forming polymer that falls within the claimed range, because Falkenhausen the desirability to use the same matrix-forming polymer to obtain the same film shape dosage form having the same disintegrating time.

Claims 13, 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falkenhausen et al., in view of Myers et al. US 2007/0122455.

Falkenhausen is relied upon for the reasons stated above. The references do not teach ethyl cellulose as firm-forming polymer.

Myers teaches a uniform film for rapid-dissolve dosage form comprising ethyl cellulose as a matrix-forming polymer (paragraph 0063). Myers further teaches the uniform film comprising a muco-adhesive layer (paragraph 0155).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Falkenhausen using ethyl cellulose as a film-forming polymer in view of the teaching of Myers, this is because Myers teaches using ethyl cellulose in rapid-dissolve film-shaped dosage form is well known in the art, and this is because Falkenhausen teaches the desirability for using cellulosic film-forming polymers.

Claims Allowable

Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 09/09/08 have been fully considered but they are not persuasive.

The rejections over Ziegler are withdrawn in view of applicant's arguments at pages 14-15, namely stated that Ziegler is not a proper prior art in view of the present application priority filing date.

Applicant argues that the gas forming agent taught by Falkenhausen might be completed at the end of the production process, therefore, the final product cannot be assumed that the resulting product would still contain any gas forming excipient. Further, Falkenhausen fails to teach the presence of a carbon dioxide-forming substance which is not combined with an acid.

However, in response to applicant's argument that the dosage form of Falkenhausen is combined with an acid, it is noted that Falkenhausen teaches the use of acid as a possibility incase the active agent is insoluble or unstable under basic condition (paragraph 0029). Accordingly, the addition of acid may not be necessary. Note the process recited in the claims of Falkenhausen does not require the addition of the acid. Further, Falkenhausen clearly teaches the use of a carbon dioxide gas forming agent in the composition, the alleged that this gas forming agent is completely disappeared from the dosage form is not supported by any declaration. Accordingly, the rejection over Falkenhausen is maintained.

Applicant argues that Pather teaches using effervescent agents as penetration enhancers. However, in accordance with the other prior art, the Pather, et al.

reference assumes that carbon dioxide-forming substances must be combined with acids. According to Pather, et al., the penetration-enhancing effect is due to the effervescent effect of the effervescent agents. However, in the case of carbon dioxide-forming substances, such as sodium bicarbonate, the addition of an acid is required in order to start and maintain the gas-forming reaction (see the Examples of Pather, et al.). Since, according to the teaching of Pather, et al., it is considered essential to produce an effervescent effect, and since carbon dioxide-forming substances must be combined with acids to support gas production, Pather, et al. could not have suggested adding a carbon dioxide-forming substance which is not combined with an acid (see, for example, paragraphs [0015] - [0017]; [0019] and [0022]). Likewise, Falkenhausen, et al. teach adding carbon dioxide-forming substances for product an effervescent (bubbling) effect which is required to produce a foamed matrix. Therefore, Falkenhausen, et al. when combined with Pather, et al. fail to teach or suggest adding a carbon dioxide-forming agent without an acid. It is respectfully submitted that it would therefore not be obvious to one skilled in the art to have combined said teachings to arrive at the presently claimed invention, and that such combination would still fail to teach every presently claimed limitation. Therefore, withdrawal of this rejection is respectfully requested.

However, in response to applicant's arguments with respect to the present of acid, the examiner is unable to determine any unexpected and/or unusual result in the absent of acid. In other words, applicant has not shown that the present of acid would detrimentally affect the desirability for obtaining a rapidly disintegrating sheet or wafer dosage form with masking taste. This fact is also evident by the present invention,

which states that with or without acid, the sensation of taste in the case of oral application according to the present invention is surprisingly, altered such that bitter-tasting substances or active agents do no longer produce this unpleasant sensation of taste (paragraph 000017, or page 5 of the PCT translation). Accordingly, the rejection over Falkenhausen and Pather is maintained.

Applicant argues that Myers, et al. was cited merely for teaching ethyl cellulose as a film-forming polymer and the reference fails to make up for the aforementioned deficiencies of Falkenhausen, et al. Therefore, it is respectfully submitted that this rejection be withdrawn.

However, according to the above argument to maintain the rejection over Falkenhausen, the rejection over Falkenhausen in view of Myers is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615